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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,393	01/13/2005	Andrew Lennard Lewis	Q82517	2458
23373 7590 12/12/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
FUBARA, BLESSING M				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
12/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,393

Applicant(s)

LEWIS, ANDREW LENNARD

Examiner

BLESSING M. FUBARA

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 33-78 is/are pending in the application.
- 4a) Of the above claim(s) 38-40, 56-63, 65, 66 and 71-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 33-37, 41-55, 64 and 67-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/29/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of preliminary amendment filed 9/29/08, response to election/restriction requirement and IDS filed 8/25/08. Claims 2-32 were canceled 7/15/2004. New claims 33-78 were added 7/15/08. Claims 33, 56, 73 and 75 are currently amended. Claims 1, 33-78 are pending.

Election/Restrictions

1. Applicant's election without traverse of claims 1, 33-37, 41-55, 64 and 67-70 in the reply filed on 8/25/08 is acknowledged. Claims 38-40, 56-63, 65, 66 and 71-78 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 33-37, 41-55, 64 and 67-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

5. Claim 1 is directed to a process in which zwitterionic monomer I is polymerized in a living radical polymerization process in the presence of catalyst and initiator. There is no

description for the product made by the process and the claims have not identified the polymer product formed. One cannot make what one does not know.

It is suggested that applicant name the product made without introducing new matter into the claims and/or specification.

6. Claims 34 and 36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 34 recites the presence of biological active moiety and R⁴³ but claim 33 does not have R⁴³.

8. Claim 36 recites the limitation "the biologically active moiety" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. Claim 36 depends from claim 33 and claim 33 does not recite biologically active moiety.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 33-35, 46-53, 64, 68-70 are rejected under 35 U.S.C. 102(a) as being anticipated by Haddleton (US 6,310,149) or applicant's admitted prior art.
11. Applicant admits having the knowledge that Haddleton uses cholesteryl-2-bromoisobutyrate initiator in the polymerization of MPC in the specification at paragraph [0131] of the published application.
12. Haddleton describes polymerizing zwitterionic monomer such as the MPC using bromoisobutyrate derivative of cholesteryl as an initiator; specifically, Haddleton says that the polymerization process is a living/pseudo process (see the abstract; column 4, lines 5-10; columns 11-17; column 18, lines 61-67; column 19, line 13; column 20, lines 47, 48).
13. Claims 1, 33-35, 46-53, 64, 68-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Haddleton (US 6,310,149).
14. Haddleton describes polymerizing zwitterionic monomer such as the MPC using bromoisobutyrate derivative of cholesteryl as an initiator; specifically, Haddleton says that the polymerization process is a living/pseudo process (see the abstract; column 4, lines 5-10; columns 11-17; column 18, lines 61-67; column 19, line 13; column 20, lines 47, 48).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1, 33-37, 41-43, 46-55, 67-70 rejected under 35 U.S.C. 103(a) as being unpatentable over Haddleton (US 6,310,149) in view of Davies et al. (WO 02/27209).

17. Haddleton has been shown above the anticipate claims 1, 33-35, 46-53, 68-70. For claims 41 and 67, it is within the technical skill of the artisan to determine the molecular weight of the product formed from the process. Polydispersity as recited in claim 42 is the property of the polymer and as such claim 42 is met. Haddleton does not teach that the product formed from the process has biologically active agents associated or that the product would be used to carry biologically active moieties. However, Davies teaches that polymers derived from MPC inner salts are capable of binding biologically active agents (abstract; page 1, lines 2, 3; page 10, lines 18-21). Therefore, taking the teachings of the prior art, one having ordinary skill in the art would have reasonable expectation that the product formed from MPC and bromoisobutyrate derivative of cholesteryl as initiator would effectively bind biologically active moieties such as the agents recited in claims 34, 36 and 37.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1, 33-37, 41-55, 64 and 67-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,562,330 in view of Haddleton (US 6,310,149).

20. The issued claims are directed to process of making polymer that does not use initiator of the type bromoisobutyrate derivative of active agents. But, Haddleton describes polymerizing MPC using bromoisobutyrate derivative of cholesteryl as an initiator. Therefore, one having ordinary skill in the art would reasonably expect that using the initiator of Haddleton would be effective to initiate the polymerization of the monomers of the type of the instant invention.

21. Claims 1, 33-35, 46-53, 64, 68-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,852,816 in view of Haddleton (US 6,310,149).

22. The process of Issued claim 1 is the same as instant claim 1 except that the issued claim 1 recited the use of generic initiator. However, the use of bromoisobutyrate derivative of cholesteryl as an initiator in living/pseudo polymerization process a process is disclosed for use with MPC by Haddleton (see the abstract; column 4, lines 5-10; columns 11-17; column 18, lines 61-67; column 19, line 13; column 20, lines 47, 48). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that using bromoisobutyrate derivative of cholesteryl as an initiator in living/pseudo polymerization process of Lewis would effectively initiate the polymerization of monomers such as MPC.

23. Claims 1, 33-37, 41-55, 64 and 67-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No.

6,852,816 in view of Haddleton (US 6,310,149) and further in view of Davies et al. (WO 02/27209).

24. US 6,852,816 in view of Haddleton has been shown to render obvious claims 1, 33-35, 46-53, 64, 68-70. But the polymer of US 6,852,816 does not have biologically active agent. However, Davies teaches that polymers derived from MPC inner salts are capable of binding biologically active agents (abstract; page 1, lines 2, 3; page 10, lines 18-21). Therefore, taking the teachings of the prior art, one having ordinary skill in the art would have reasonable expectation that the product formed from MPC and bromoisobutyrate derivative of cholesteryl as initiator would effectively bind biologically active moieties such as the agents recited in claims 34, 36 and 37.

25. Claims 1, 33-37, 41-55, 64 and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 23 and 36-43 of copending Application No. 10/506,814 in view of Haddleton (US 6,310,149).

26. The copending claims teach the examined process except that the copending claims do not use an initiator of the type recited in the claims. But, the use of bromoisobutyrate derivative of cholesteryl as an initiator in living/pseudo polymerization process a process is disclosed for use with MPC by Haddleton (see the abstract; column 4, lines 5-10; columns 11-17; column 18, lines 61-67; column 19, line 13; column 20, lines 47, 48). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that using bromoisobutyrate derivative of cholesteryl as an initiator in living/pseudo polymerization process of Lewis would effectively initiate the polymerization of monomers such as MPC.

This is a provisional obviousness-type double patenting rejection.

27. Claims 1, 33-37, 41-55, 64 and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-44 of copending Application No. 10/544,113. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated, or would have been obvious, over the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 29-44 anticipate claims 1, 33-37, 41-55, 64 and 67-70.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claims 1, 33-37, 41-55, 64 and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44-100 of copending Application No. 10/542333. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated, or would have been obvious, over the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 44-100 anticipate claims 1, 33-37, 41-55, 64 and 67-70.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618